DEC 21 2000

K000714

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): AJW Technology Consultants, Inc.
962 Allegro Ln.
Apollo Beach, FL 33572

Phone: 813-645-2855
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Contact Person: Art Ward

Date of Summary: December 11, 1999

Trade Name: MEDPRO VACUFLOW+ Safe Blood Collection Set

Classification Name: Blood Specimen Collection Device
21 CFR Section 862.1675

Predicate Device: K980414 Vacutainer Safety- Lok BC Set Becton Dickinson

Device Description/ Comparison: The MEDPRO VACUFLOW+ is a blood collection set comprised of a winged needle, ¾ inch long in 21, 23 and 25 gauge with a 12 inch sample collection tube with multi-sample adapter and optional tube holder. The device is sterile, single patient use.

Intended Use: The VACUFLOW+ Blood Collection Set is a sterile, multiple sample, single use device. One end of the set has attached a multi-sample luer adapter, which can and usually is connected to a tube holder from which blood is drawn through a vacutainer and the other is a needle for performing venipuncture for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle to help protect against accidental needle sticks during normal handling and disposal.

510(K) Summary
Differences and Similarities

As reviewed in Section 9 the VACUFLOW+ Blood Collection Set is fundamentally similar to the predicate device. This summary reviews the:

Intended Use
Applications
Usage Location
Technological characteristics

Intended Use:

Both the VACUFLOW+ and predicate device have the same intended use for the collection of blood by venipuncture.

Applications:

Both the MED-PRO and the predicate product are used for the collection of blood in clinical settings.

Usage Location:

The VACUFLOW+ and predicate device are designed for use within a laboratory, hospital, physician's office or other clinical setting.

Technological Characteristics:

These products have very similar technology in their components.

Similarities:

All devices are sterile, single patient use, with a safety shield to help protect against accidental needle sticks.
The MED-PRO and Becton Dickinson Safety-Lok Blood Collection Set both have 12" sample tubing with Multi-Sample luer adapter.
The MED-PRO device is packaged in either 20 or 50 unit packs. The Becton Dickinson Safety-Lok Blood Collection Set is packaged in 50 unit packs.
The stainless steel venipuncture needle is ¾" long and available in different gauge sizes on the MED-PRO device and the BD Safety-Lok Blood Collection Set.
The MED-PRO unit is packed in one tyvek sided polyethylene pouch, as is the B-D unit.

Differences:

The MED-PRO device offers an optional tube holder.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

MED-PRO Technologies, Incorporated
C/O Mr. Arthur Wards
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K000714
Trade Name: VACUFLOW+SAFE Blood Collection Set
Regulatory Class: II and II
Product Code: FMI and JKA
Dated: November 22, 2000
Received: November 28, 2000

Dear Mr. Wards:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000714

Device Name: VACUFLOW+ Blood Collection System

Indications For Use:

The VACUFLOW+ Blood Collection Set is a sterile, multiple sample, single use device. One end of the set has attached a multi-sample luer adapter, which can and is usually connected to a tube holder from which blood is drawn through a vacutainer and the other is a needle for performing venipuncture for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle to help protect against accidental needle sticks during normal handling and disposal.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cascetta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000714